

HFA-305
Documents Management Branch

Approval Date:

FREEDOM OF INFORMATION SUMMARY
ORIGINAL NEW ANIMAL DRUG APPLICATION
NADA 141-201

**Chlortetracycline (Aureomycin®) and
Laidlomycin propionate potassium (Cattlyst®)**

- 1) (10 mg/lb of body weight CTC and 5 g/ton laidlomycin) - For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency and increased rate of weight gain in cattle being fed in confinement for slaughter.
- 2) (10 mg/lb of body weight CTC and 5 to 10 g/ton laidlomycin) - For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency in cattle being fed in confinement for slaughter.
- 3) (350 mg/hd/day CTC and 5 g/ton laidlomycin) - For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline; and for improved feed efficiency and increased rate of weight gain in cattle being fed in confinement for slaughter.
- 4) (350 mg/hd/day CTC and 5 to 10 g/ton laidlomycin) - For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline; and for improved feed efficiency in cattle being fed in confinement for slaughter.

Sponsored by:
Alpharma Inc.
One Executive Drive
P.O. Box 1399
Fort Lee, New Jersey 07024

NADA 141-201

FOIS.

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FREEDOM OF INFORMATION SUMMARY

Combined use of Aureomycin® and Cattlyst® in Cattle Feeds

1. GENERAL INFORMATION:

- a. File Number: NADA 141-201
- b. Sponsor: Alpharma Inc.
One Executive Drive
P.O. Box 1399
Fort Lee, New Jersey 07024

Drug Labeler Code: 046573
- c. Established Names: Chlortetracycline
Laidlomycin propionate potassium
- d. Proprietary Names: Aureomycin®
Cattlyst®
- e. Dosage Form: Type A medicated articles
- f. How Supplied: Aureomycin® 50 lb. bags
Cattlyst® 50 lb. bags
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Chlortetracycline: 50 to 100 grams of
chlortetracycline activity per pound.
Laidlomycin propionate potassium: 50 grams
of laidlomycin propionate potassium activity
per pound.
- i. Route of Administration: Orally via the feed
- j. Species/Class: Cattle
- k. Recommended Dosage: Chlortetracycline - 1) 10 mg/lb of body
weight for the treatment of bacterial
enteritis caused by *E. coli* and bacterial
pneumonia caused by *P. multocida*
organisms susceptible to chlortetracycline;

and 2) 350 mg/head/day for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline.

Laidlomycin propionate potassium - 1) 5 g/ton for improved feed efficiency and increased rate of weight gain; and 2) 5 to 10 g/ton for improved feed efficiency.

1. Pharmacological Category:

Antimicrobial and ionophore

m. Indications:

1) (10 mg/lb of body weight CTC and 5 g/ton laidlomycin) - For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency and increased rate of weight gain in cattle being fed in confinement for slaughter.

2) (10 mg/lb of body weight CTC and 5 to 10 g/ton laidlomycin) - For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency in cattle being fed in confinement for slaughter.

3) (350 mg/hd/day CTC and 5 g/ton laidlomycin) - For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline; and for improved feed efficiency and increased rate of weight gain in cattle being fed in confinement to slaughter.

4) (350 mg/hd/day CTC and 5 to 10 g/ton laidlomycin) - For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline; and for

improved feed efficiency in cattle being fed in confinement to slaughter.

2. EFFECTIVENESS:

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in animal feed have previously been separately approved for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on effectiveness grounds unless the Agency finds that the NADA fails to demonstrate that:

- there is substantial evidence to indicate that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the labeled effectiveness.
- each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population.
- where the combination contains more than one nontopical antibacterial active ingredient/animal drug, there is substantial evidence that each of the nontopical antibacterial active ingredients or animal drugs makes a contribution to the labeled effectiveness.

Chlortetracycline, as provided by Alpharma Inc., has previously been separately approved for use in cattle feed for (1) the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline and (2) control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline (21 CFR 558.128(d)(1)(xii) and (xvii)). Laidlomycin propionate potassium, as provided by Alpharma Inc., has previously been separately approved for use in cattle feed for improved feed efficiency and increased rate of weight gain (21 CFR 558.305(d)(1 and 2)). Effectiveness for each drug, chlortetracycline and laidlomycin propionate potassium, when administered alone in accordance with its approved uses and conditions of use, is demonstrated in Alpharma Inc.'s approved NADAs 48-761 and 141-025, respectively.

Because chlortetracycline and laidlomycin propionate potassium each have at least one use that is different from the other animal drug used in the combination, the NADA must also demonstrate that chlortetracycline plus laidlomycin propionate potassium provide appropriate concurrent use for the intended target population. The use of chlortetracycline and laidlomycin propionate potassium provides appropriate concurrent use because these drugs are intended to treat different conditions (chlortetracycline, bacterial enteritis and bacterial

pneumonia; laidlomycin propionate potassium, feed efficiency and weight gain) likely to occur simultaneously with sufficient frequency in cattle fed in confinement for slaughter. Laidlomycin propionate potassium is not considered to be an antibacterial animal drug for such use in cattle for the purposes of Section 512(d)(4) of the FFDCA, because laidlomycin propionate potassium is approved only for improved feed efficiency and increased rate of weight gain in cattle fed in confinement for slaughter.

3. TARGET ANIMAL SAFETY:

In accordance with the FFDCA, as amended by the Animal Drug Availability Act of 1996, if the active ingredients or animal drugs intended for use in combination in animal feed have previously been separately approved for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on target animal safety grounds unless:

- there is a substantiated scientific issue specific to an active ingredient or animal drug used in the combination that cannot adequately be evaluated based on the information contained in the application for the combination, and FDA finds that the application fails to show that the combination is safe, or
- a scientific issue is raised by target animal observations contained in the studies submitted to the NADA for the combination, and FDA finds that the application fails to show that the combination is safe.

Chlortetracycline, as provided by Alpharma Inc., has previously been separately approved for use in cattle feed for (1) the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline and (2) control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline (21 CFR 558.128(d)(1)(xii) and (xvii)). Laidlomycin propionate potassium, as provided by Alpharma Inc., has previously been separately approved for use in cattle feed for improved feed efficiency and increased rate of weight gain (21 CFR 558.305(d)(1 and 2)). Effectiveness for each drug, chlortetracycline and laidlomycin propionate potassium, when administered alone in accordance with its approved uses and conditions of use, is demonstrated in Alpharma Inc.'s approved NADAs 48-761 and 141-025, respectively.

Target animal safety for each drug, chlortetracycline and laidlomycin propionate potassium, when administered alone in accordance with its approved uses and conditions of use, is demonstrated in Alpharma Inc.'s approved NADAs 48-761 and 141-025, respectively. The Agency has found no substantiated scientific issue relating to the target animal safety of chlortetracycline and laidlomycin propionate potassium when used in combination under this NADA and no scientific issue has been raised by target animal observations submitted as part of the NADA for this combination. Thus, pursuant to FFDCA, as amended by the Animal

Drug Availability Act of 1996, no specific target animal safety studies are required for approval of NADA 141-201.

4. HUMAN SAFETY:

In accordance with the FFDCa, as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in animal feed have previously been separately approved for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on human safety grounds unless FDA finds that the application fails to establish that:

- none of the active ingredients or animal drugs used in the combination at the longest withdrawal for any of the active ingredients or animal drugs in the combination exceeds the established tolerance, or
- none of the active ingredients or animal drugs in the combination interferes with the method of analysis for another active ingredient or drug in the combination.

A. Toxicity:

Safety of this combination product has been established by data in NADA 48-761 for chlortetracycline and NADA 141-025 for laidlomycin propionate potassium. An Acceptable Daily Intake (ADI) of 0.025 mg/kg body weight/day has been established for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline (proportioned as 40% to tissues and 60% to milk).

B. Tolerances for Residue:

For chlortetracycline, tolerances of 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney in cattle have been previously codified under 21 CFR 556.150.

C. Residue Data:

The in-life portion of the following study (Study No. CD-99-20) was conducted at Roche Vitamins Inc., Wrightstown, NJ, with assays conducted at Analytical Development Corporation, Colorado Springs, CO, and Colorado Animal Research Enterprises (CARE), Fort Collins, CO, to establish that, with a zero withdrawal time, chlortetracycline in the presence of laidlomycin propionate potassium does not exceed its established tolerance, that laidlomycin propionate potassium in the presence of chlortetracycline does not exceed the residue in cattle fed only laidlomycin, and that the presence of the drugs in the same cattle tissue do not interfere with the assay for either drug.

Eighteen cattle were assigned to three treatment groups consisting of a nonmedicated control group, a laidlomycin-only medicated treatment group, and a chlortetracycline and laidlomycin medicated treatment group. Crossbred control cattle (1 steer, 1 heifer) were fed unmedicated feed for 14 days. Crossbred laidlomycin-only medicated cattle (4 steers, 4 heifers) received feed containing 150 mg laidlomycin propionate potassium/head/day for 14 days. Crossbred laidlomycin and chlortetracycline medicated cattle (4 steers, 4 heifers) received feed containing 150 mg laidlomycin propionate potassium/head/day and 10 mg chlortetracycline/lb bodyweight/day for 14 days. All cattle were slaughtered within 12 hours after removing the feed. Liver and kidney tissues were collected and analyzed for residue. Laidlomycin liver residues were measured using an HPLC method. Chlortetracycline kidney residues were determined by the approved microbiology method.

Mean Residues at Zero Withdrawal of Laidlomycin in Liver (ppm) and Chlortetracycline in Kidney (ppm) Collected from Cattle Treated with Medicated Feed Containing 150 mg laidlomycin propionate potassium/head/day alone for 14 days or in Combination with 10 mg chlortetracycline/lb bodyweight/day for 14 days		
Treatment Group	Laidlomycin	Chlortetracycline
Laidlomycin Alone	0.062 \pm 0.031	---
Laidlomycin Plus Chlortetracycline	0.055 \pm 0.017	1.266 \pm 0.376

LOQ for laidlomycin in liver = 0.050 ppm

LOQ for chlortetracycline in kidney = 0.025 ppm

Samples of control kidney were fortified with chlortetracycline and laidlomycin. The data showed that the presence of laidlomycin did not interfere with the assay of chlortetracycline and the presence of chlortetracycline did not interfere with the assay of laidlomycin.

Residues of chlortetracycline in kidney of cattle medicated with chlortetracycline and laidlomycin were less than the established tolerance limit of 12 ppm at twelve hours withdrawal, thereby confirming the established zero hour withdrawal period for chlortetracycline, as well as indicating an absence of interference. Residues of laidlomycin in liver of cattle medicated with laidlomycin plus chlortetracycline did not differ significantly ($p = 0.605$) from those of cattle medicated with laidlomycin alone, thereby confirming the established zero hour withdrawal period for laidlomycin.

D. Regulatory Methods for Residues:

The regulatory method for detection of chlortetracycline residues is a cylinder-plate microbiology method using *Bacillus cereus* var. *mycoides* (ATCC 11778) as the test organism ("Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols", Food and Drug Administration, Washington, D.C., 1968).

Laidlomycin residues are measured by an HPLC method. The methods are on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512(d)(4) of the FFDCA and 21 CFR Part 514 of the implementing regulations. Chlortetracycline (10 mg/lb of bodyweight or 350 mg/head/day) plus laidlomycin propionate potassium (5 g/ton or 5 to 10 g/ton) are safe and effective for the claims indicated in section 1 of this FOI Summary.

Pursuant to 21 CFR 514.106(b)(2), this combination NADA approval is regarded as a Category II supplemental change which did not require a reevaluation of safety and efficacy data in the parent NADAs.

The drugs are to be fed in Type C medicated feeds in accordance with section 1 of the FOI Summary and the Blue Bird labeling that is attached to this document.

The Center for Veterinary Medicine has concluded that, for this product, adequate directions of use by the layperson have been provided and the product will have over-the-counter (OTC) status. Label directions provide detailed instruction in plain language. The drug products are not controlled substances. Thus, the combination is assigned OTC status, and the labeling is adequate for the intended use.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

Type B Medicated Feed (Blue Bird)

BLUEBIRD AUREOMYCIN[®] (10 mg/lb. BW) + CATTLYST[®] (5 g/ton)
BLUEBIRD AUREOMYCIN[®] (10 mg/lb. BW) + CATTLYST[®] (5-10 g/ton)
BLUEBIRD AUREOMYCIN[®] (350 mg/lb. BW) + CATTLYST[®] (5 g/ton)
BLUEBIRD AUREOMYCIN[®] (350 mg/lb. BW) + CATTLYST[®] (5-10 g/ton)

Type C Medicated Feed (Blue Bird)

BLUEBIRD AUREOMYCIN[®] (10 mg/lb. BW) + CATTLYST[®] (5 g/ton)
BLUEBIRD AUREOMYCIN[®] (10 mg/lb. BW) + CATTLYST[®] (5-10 g/ton)
BLUEBIRD AUREOMYCIN[®] (350 mg/lb. BW) + CATTLYST[®] (5 g/ton)
BLUEBIRD AUREOMYCIN[®] (350 mg/lb. BW) + CATTLYST[®] (5-10 g/ton)

BLUEBIRD AUREOMYCIN® (10 mg/lb. BW) + CATTLYST® (5 g/ton)
Type B Cattle Feed
Medicated

For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline, and for improved feed efficiency and increased rate of weight gain in cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline4444 to 80,000 g/ton
Laidlomycin propionate potassium33.3 to 600 g/ton

Guaranteed Analysis

Crude protein, not less than %
Crude fat, not less than %
Crude fiber, not more than %
Calcium, not less than %
Calcium, not more than %
Phosphorus, not less than %
Potassium, not less than %
Salt¹, not less than %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Mixing Directions

In order to treat cattle for bacterial enteritis and/or pneumonia while improving feed efficiency and increasing rate of weight gain, mix this Type B medicated feed with non-medicated feed ingredients to manufacture one ton of complete cattle feed containing 500 to 2000 grams chlortetracycline and 5 grams laidlomycin propionate potassium. The following table provides examples of mixing rates.

Body Wt., lb.	Feed Consumption, lb./head/day	Type B Concentration, g/ton		Type B per ton of Type C, lb.	Non-Medicated Feed per ton of Type C, lb.	Type C Concentration, g/ton	
		Chlortetracycline	Laidlomycin			Chlortetracycline	Laidlomycin
500	12	5555.6	33.3	300	1700	833.3	5
600	12	10000.0	50.0	200	1800	1000.0	5
800	20	6000.0	37.5	266.7	1733.3	800.0	5
1000	20	3600.0	18.0	555.6	1444.4	1000.0	5
1000	30	6666.7	500.0	20.0	1980	666.7	5
1200	30	45000.0	281.3	35.6	1964.4	800.0	5

The resulting Type C medicated feed should be fed continuously at a rate to provide 10 mg chlortetracycline per lb. body weight per day and 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days.

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

*Final printed label on formulated Type B Medicated feed must bear a single concentration for each drug.

(OVER)

BLUEBIRD AUREOMYCIN® (10 mg/lb. BW) + CATTLYST® (5-10 g/ton)
Type B Cattle Feed
Medicated

For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline, and for improved feed efficiency in cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline 4000 to 80,000 g/ton
Laidlomycin propionate potassium 33.3 to 1200 g/ton

Guaranteed Analysis

Crude protein, not less than %
Crude fat, not less than %
Crude fiber, not more than %
Calcium, not less than %
Calcium, not more than %
Phosphorus, not less than %
Potassium, not less than %
Salt¹, not less than %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Mixing Directions

In order to treat cattle for bacterial enteritis and/or pneumonia while improving feed efficiency, mix this Type B medicated feed with non-medicated feed ingredients to manufacture one ton of complete cattle feed containing 500 to 4000 grams chlortetracycline and 5 to 10 grams laidlomycin propionate potassium. The following table provides examples of mixing rates.

Body Wt., lb.	Feed Consumption, lb./head/day	Type B Concentration, g/ton		Type B per Ton of Type C, lb.	Non-Medicated Feed per Ton of Type C, lb.	Type C Concentration, g/ton	
		Chlortetracycline	Laidlomycin			Chlortetracycline	Laidlomycin
500	8	10000.0	60.0	250	1750	1250.0	7.5
600	6	20000.0	100.0	200	1800	2000.0	10
600	12	6666.7	33.3	300	1700	1000.0	5
800	20	6000.0	37.5	266.7	1733.3	800.0	5
1000	6	12000.0	36.0	555.6	1444.4	3333.3	10
1000	30	66666.7	500.0	20.0	1980	666.7	5

The resulting Type C medicated feed should be fed continuously at a rate to provide 10 mg chlortetracycline per lb. body weight/day and 30 to 150 mg laidlomycin propionate potassium per head per day for not more than 5 days.

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

*Final printed label on formulated Type B Medicated feed must bear a single concentration for each drug.

(OVER)

BLUEBIRD AUREOMYCIN® (350 mg/head) + CATTLYST® (5 g/ton)
TYPE B Cattle Feed
Medicated

For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, and for improved feed efficiency and increased rate of weight gain in beef cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline 155.6 to 4666.7 g/ton
Laidlomycin propionate potassium 33.3 to 1000 g/ton

Guaranteed Analysis

Crude protein, not less than %
Crude fat, not less than %
Crude fiber, not more than %
Calcium, not less than %
Calcium, not more than %
Phosphorus, not less than %
Potassium, not less than %
Salt¹, not less than %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Mixing Directions

In order to control bacterial pneumonia while improving feed efficiency and increasing rate of weight gain, mix this Type B medicated feed with non-medicated feed ingredients to manufacture 1 ton of complete Type C medicated cattle feed containing 23.3 to 58.3 grams chlortetracycline and 5 grams laidlomycin propionate potassium. The following table provides examples of mixing rates.

Feed Consumption, lb./head/day	Type B Concentration, g/ton		Type B per ton Type C, lb.	Non-Medicated Feed per Ton Type C, lb.	Type C Concentration, g/ton	
	Chlortetracycline	Laidlomycin			Chlortetracycline	Laidlomycin
12	388.9	33.3	300	1700	58.3	5
15	466.7	50.0	200	1800	46.7	5
20	700.0	100.0	100	1900	35.0	5
30	155.6	33.3	300	1700	23.3	5
30	4666.7	1000	10	1990	23.3	5

The resulting Type C medicated feed should be fed continuously at a rate to provide 350 mg chlortetracycline per head per day and 30 to 75 mg laidlomycin propionate potassium per head per day.

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

*Final printed label on formulated Type B Medicated feed must bear a single concentration for each drug.

(OVER)

BLUEBIRD AUREOMYCIN® (350 mg/head) + CATTLYST® (5-10 g/ton)
TYPE B Cattle Feed
Medicated

For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, and for improved feed efficiency in beef cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline 127.3 to 4666.7 g/ton
Laidlomycin propionate potassium 33.3 to 2000 g/ton

Guaranteed Analysis

Crude protein, not less than %
Crude fat, not less than %
Crude fiber, not more than %
Calcium, not less than %
Calcium, not more than %
Phosphorus, not less than %
Potassium, not less than %
Salt¹, not less than %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Feeding Directions

In order to control bacterial pneumonia and improve feed efficiency, mix this Type B medicated feed with non-medicated feed ingredients to manufacture 1 ton of complete Type C medicated cattle feed containing 14.6 to 116.7 grams chlortetracycline and 5 to 10 grams laidlomycin propionate potassium. The following table provides examples of mixing rates.

Feed Consumption, lb./head/day	Type B Concentration, g/ton		Type B per ton Type C, lb.	Non-Medicated Feed per ton Type C, lb.	Type C Concentration, g/ton	
	Chlortetracycline	Laidlomycin			Chlortetracycline	Laidlomycin
12	388.9	33.3	300	1700	58.3	5
15	466.7	50.0	200	1800	46.7	5
20	700.0	150.0	100	1900	35.0	7.5
20	350.0	100.0	200	1800	35.0	10
30	155.6	50.0	300	1700	23.3	7.5
30	4666.7	2000.0	10	1990	23.3	10
36	3888.9	1500.0	10	1990	19.4	7.5

The resulting Type C medicated feed should be fed continuously at a rate to provide 350 mg chlortetracycline per head per day and 30 to 150 mg laidlomycin propionate potassium per head per day.

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

*Final printed label on formulated Type B Medicated feed must bear a single concentration for each drug.

(OVER)

BLUEBIRD AUREOMYCIN® (10 mg/lb. BW) + CATTLYST® (5 g/ton)
TYPE C Cattle Feed
Medicated

For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline, and for improved feed efficiency and increased rate of weight gain in cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline 500 to 2000 g/ton
Laidlomycin propionate potassium 5 g/ton

Guaranteed Analysis

Crude protein, not less than %
Crude fat, not less than %
Crude fiber, not more than %
Calcium, not less than %
Calcium, not more than %
Phosphorus, not less than %
Potassium, not less than %
Salt¹, not less than %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Feeding Directions

Provide this Type C medicated feed to confined cattle to treat bacterial enteritis and/or pneumonia while improving feed efficiency and increasing rate of weight gain. Feed continuously at a rate of 10 mg chlortetracycline per lb. body weight per day and 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. The following table provides examples of feeding rates and amount of drug per ton of feed.

Body Wt., lb.	Feed Consumption		Chlortetracycline		Laidlomycin	
	% Body Wt.	lb./head /day	Dose, mg/lb. BW/day	Feeding Rate, g/ton	Dose, mg/head/day	Feeding Rate, g/ton
500	2.5	12.5	10	800	31	5
600	2	12	10	1000	30	5
800	2.5	20	10	800	50	5
1000	3	30	10	667	75	5

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding. If manufactured using liquid Type B laidlomycin propionate potassium feed, this dry Type C medicated feed expires 7 days after the date of manufacture.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

*Final printed label on formulated Type C Medicated feed must bear a single concentration for each drug.

(OVER)

BLUEBIRD AUREOMYCIN® (10 mg/lb. BW)+ CATTLYST® (5-10 g/ton)
TYPE C Cattle Feed
Medicated

For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline, and for improved feed efficiency in cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline 500 to 4000 g/ton
Laidlomycin propionate potassium 5 to 10 g/ton

Guaranteed Analysis

Crude protein, not less than %
Crude fat, not less than %
Crude fiber, not more than %
Calcium, not less than %
Calcium, not more than %
Phosphorus, not less than %
Potassium, not less than %
Salt¹, not less than %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Feeding Directions

Provide this Type C medicated feed to confined cattle to treat bacterial enteritis and/or pneumonia while improving feed efficiency. Feed continuously at a rate of 10 mg chlortetracycline per lb. body weight per day and 30 to 150 mg laidlomycin propionate potassium per head per day for not more than 5 days. The following table provides examples of feeding rates and amount of drug per ton of feed.

Body Wt. Lb.	Feed Consumption		Chlortetracycline		Laidlomycin	
	% Body Wt.	lb./head/day	Dose, mg/lb./day	Feeding Rate, g/ton	Dose, mg/head/day	Feeding Rate g/ton
500	2	10	10	1000	30	6
	2	10	10	1000	50	10
	3	15	10	667	38	5
	3	15	10	667	75	10
1000	2	20	10	1000	50	5
	2	20	10	1000	100	10
	3	30	10	667	75	5
	3	30	10	667	150	10

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding. If manufactured using liquid Type B laidlomycin propionate potassium feed, this dry Type C medicated feed expires 7 days after the date of manufacture.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

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(OVER)

BLUEBIRD AUREOMYCIN® (350 mg/head) + CATTLYST® (5 g/ton)
TYPE C Cattle Feed
Medicated

For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, and for improved feed efficiency and increased rate of weight gain in beef cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline23.3 to 58.3 g/ton
Laidlomycin propionate potassium5 g/ton

Guaranteed Analysis

Crude protein, not less than..... %
Crude fat, not less than..... %
Crude fiber, not more than..... %
Calcium, not less than %
Calcium, not more than..... %
Phosphorus, not less than %
Potassium, not less than..... %
Salt¹, not less than..... %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Feeding Directions

Provide this Type C medicated feed to confined beef cattle to control bacterial pneumonia while improving feed efficiency and increasing rate of weight gain. Feed continuously at a rate of 350 mg chlortetracycline per head per day and 30 to 75 mg laidlomycin propionate potassium per head per day. The following table provides examples of feeding rates and amount of drug per ton of feed.

Body Wt., lb.	Feed Consumption		Chlortetracycline		Laidlomycin	
	% Body Wt.	lb./head/day	Dose, mg/head/day	Feeding Rate, g/ton	Dose, mg/head/day	Feeding Rate g/ton
500	2.5	12.5	350	56	31.3	5
600	2	12	350	58.3	30	5
800	2.5	20	350	35	50	5
1000	3	30	350	23.3	75	5

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding. If manufactured using liquid Type B laidlomycin propionate potassium feed, this dry Type C medicated feed expires 7 days after the date of manufacture.

NET WEIGHT ON BAG OR BULK

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(OVER)

BLUEBIRD AUREOMYCIN® (350 mg/head) + CATTLYST® (5-10 g/ton)**TYPE C Cattle Feed****Medicated**

For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, and for improved feed efficiency in beef cattle fed in confinement for slaughter.

Active Drug Ingredients*

Chlortetracycline 14.6 to 116.7 g/ton
Laidlomycin propionate potassium 5 to 10 g/ton

Guaranteed Analysis

Crude protein, not less than %
Crude fat, not less than %
Crude fiber, not more than %
Calcium, not less than %
Calcium, not more than %
Phosphorus, not less than %
Potassium, not less than %
Salt¹, not less than %
Salt¹, not more than %
Sodium², not less than %
Sodium², not more than %
Vitamin A¹ (not less than) IU/lb.

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Ingredients as defined by AAFCO

Feeding Directions

Provide this Type C medicated feed to confined beef cattle to control bacterial pneumonia while improving feed efficiency. Feed continuously at a rate of 350 mg chlortetracycline per head per day and 30 to 150 mg laidlomycin propionate potassium per head per day. The following table provides examples of feeding rates and amount of drug per ton of feed.

Body Wt. Lb.	Feed Consumption		Chlortetracycline		Laidlomycin	
	% Body Wt.	lb./head/day	Dose, mg/head/day	Feeding Rate, g/ton	Dose, mg/head/day	Feeding Rate, g/ton
500	2	10	350	70	30	6
	2	10	350	70	50	10
	3	15	350	46.7	37.5	5
	3	15	350	46.7	75	10
1000	2	20	350	35	50	5
	2	20	350	35	100	10
	3	30	350	23.3	75	5
	3	30	350	23.3	150	10

Warning

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution

Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium. The safety of laidlomycin propionate potassium in unapproved species has not been established. Not for use in animals intended for breeding. If manufactured using liquid Type B laidlomycin propionate potassium feed, this dry Type C medicated feed expires 7 days after the date of manufacture.

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